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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,569	06/29/2000	Mario Bigazzi	67206	7698

23872 7590 11/04/2002

MCGLEW & TUTTLE, PC
SCARBOROUGH STATION
SCARBOROUGH, NY 10510

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/04/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/606,569

Applicant(s)

BIGAZZI, MARIO

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Status of Application, Amendments and/or Claims

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01 April 2002 (Paper No. 10) has been entered.

The amendment filed 01 April 2002 (Paper No. 11) has been entered in full. The Terminal Disclaimer filed 23 April 2002 (Paper No. 12) has been entered in full. The amendment filed 23 April 2002 (Paper No. 14) has been entered in full. The amendment filed 23 April 2002 (Paper No. 16) has been entered in full. Claims 1-5 are under examination.

The instant application complies with the sequence rule requirements of 37 CFR 1.821-1.825.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claims 1-5 under 35 USC 112, second paragraph as set forth at pages 3-6 of the previous Office Action (01 November 2001, Paper No. 8) is *withdrawn* in view of Applicant's arguments and literature submitted (01 April 2002, Paper No. 11 and 23 April 2002, Paper No. 14).

The rejection of claims 1-5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-28 of U.S. Patent No. 5,952,296 (cited in IDS, Paper No. 2) in view of Piccinni *et al.* (Neuroimmunomodulation 917: 844-852, 2000) as set forth at pages 3-6 of the previous Office Action (04 April 2001, Paper No. 5) is *withdrawn* in view of Applicant's arguments (01 April 2002, Paper No. 11).

Information Disclosure Statement

The literature submitted in the amendment (23 April 2002, Paper No. 14) teaches that Th1 cells secrete IFN- γ (page 5, 4th paragraph). Since Th2 cells produce IL-4 and IL-5 and react with common environmental allergens, they are involved in pathogenesis of allergic IgE mediated reactions (page 6, 1st–2nd paragraph). Relaxin favors development of IFN- γ (page 7, 1st paragraph). Helminths and environmental allergens promote Th2 cell development. Extracellular pathogens, soluble antigens and oral immunization promote Th2 dominated responses (page 7, 2nd paragraph).

DeKruyff teaches the immunotherapy of converting a Th2 response into a Th1 response. The adjuvant administered induces a Th1 immune response and suppresses a Th2 allergic immune response such as to reverse a condition-associated asthma (page 9, 4th paragraph). Lastly, the literature teaches that asthma is a Th2 dominated disorder (page 10, 2nd paragraph, page 11, 1st paragraph, page 12, 2nd paragraph, page 13, 2nd paragraph, page 14, 2nd paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bani *et al.* (Endocrinology 138/5: 1909-1915, 1997) in view of Masini *et al.* (Abstract, Inflammation Research 44 (Suppl. 1) S12-S13, 1995).

The instant claims are generally drawn to a method of treating a Th2 dominated disease in a patient, method of inhibiting a pathogenic Th2 response in a human patient, method of stimulating the development of activated human T cells into Th1-like effectors, inducing endogenous IFN- γ production for inhibiting pathogenic Th2 response and enhancing Th1 response of the immunological system for relieving Th2 dominated disease.

Bani teaches that relaxin counteracts the respiratory and histopathological abnormalities of an experimentally induced asthma-like reaction in guinea pigs. Bani discloses the possibility of new therapeutic strategies for allergic asthma in humans using relaxin (abstract). Bani does not teach the administration of relaxin in humans.

Masini teaches that relaxin inhibits histamine release from isolated rat serosal mast cells. Masini discloses the possibility that relaxin or relaxin derived drugs may be used to treat allergic and peripheral vascular diseases.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Bani regarding the administration of relaxin to guinea pigs to treat asthma-like reactions, because Bani teaches that in the guinea pig, repeated exposure to antigen has been demonstrated to cause airway hyperresponsiveness and leukocyte infiltration of lung tissue mimicking histological and pharmacological correlates of asthma in humans. The motivation and expected success is provided by Bani, who demonstrates that allergic asthma in guinea pigs can be treated with relaxin and Bani and Masini who disclose that relaxin may be used in therapeutics to treat allergic conditions. In addition, asthma is inherently a Th2-dominated disease, Th1 cells inherently secrete IFN- γ and relaxin inherently favors development of IFN- γ . IFN- γ will have the inherent biological activity of enhancing a Th1 response or stimulating Th1-like effectors.

Conclusion

No claims are allowed.

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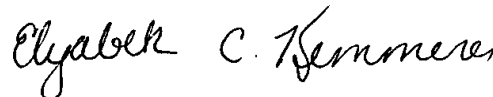
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

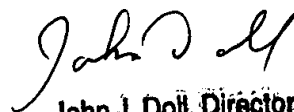
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
October 31, 2002



ELIZABETH KEMMERER
PRIMARY EXAMINER



John J. Doll, Director
Technology Center 1600